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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/646,111 | 11/20/2000 | Christopher Marriott | REF/MARIOTT/ | 3979 |

7590 12/09/2003

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| EXAMINER |
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TRAN, SUSAN T

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 12/09/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,111

Applicant(s)

MARRIOTT ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-49 and 52 is/are rejected.
- 7) ☒ Claim(s) 50 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 20.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time and Amendment filed 09/16/03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites the limitation "the substance" in 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 43 recites the limitation "the medium" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 44 recites the limitation "the medium" in 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 46 recites the limitation "the substance" in 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 50 recites the limitation "the substance" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-49, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. US 4,725,387, in view of Trofast et al. WO 95/05805.

Hirao teaches a process of shaping crystals of sugar alcohols by obtaining a saccharified starch solution with high maltose content, allowing crystallization, and separating the crystallized solid (column 2, lines 38 through column 3, lines 1-11). The viscosity of the solution can be regulated by the addition of water-soluble organic solvent, or elevated temperature (column 4, lines 45-68; and example 1). Hirao does not teach the viscosity of less than 25 Pas at a shear rate of 1s^{-1} . However, no criticality is seen in the particular viscosity since Hirao obtains the same result desired by the applicant, e.g., a crystalline composition that is non-hygroscopic, free flowing, and can be in any desire size and shape (column 7, lines 33-53). Accordingly, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable viscosity of the solution to obtain the claimed invention.

Hirao does not teach the solid crystals can be used for inhalation. However, Hirao in column 5, lines 20-58 teaches besides anhydrous crystals of maltitol, *other sugar alcohols such as sorbitol, maltotriitol and maltotetraitol* can be used for various

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uses, e.g., for foods, cosmetics, and *drugs*. Hirao further teaches that maltitol or crystalline mixture solid can be prepared into desirable shape, including granule with a granulizer (column 7, lines 66 through column 8, lines 1-4).

Trofast teaches a stable crystalline form of fine-grained substance or substance mixture useful for inhalation (page 4, lines 23-30). The substance includes salbutamol sulfate, ipratropium bromide, or salmeterol xinafoate (page 7, lines 26 through page 8, lines 1-3). The substance may be combined with carriers suitable for inhalation, such as lactose, maltose, maltitol, starch, and its hydrates (page 6, lines 21-31). Thus, it would have been obvious for one of ordinary skill in the art to optimize the solid crystalline mixture of Hirao as a carrier useful for inhalation of pharmaceutical formulation in view of the teachings of Trofast, because the references teach the advantageous result in the use of carrier, such as maltitol and lactose monohydrate as a carrier for inhalation formulation.

Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. in view of Trofast et al., and Douglas et al. US 5,635,200.

Hirao and Trofast are relied upon for the reasons stated above. The references are silent as to the teaching of carbomer as a starch or binder in an aqueous solution. However, carbomer is a well known starch or thickener, or binder in pharmaceutical art. Douglas teaches an oral administration composition comprising starch or carbopol as an aqueous solution thickener (column 7, lines 22-32). Hence, it would have been obvious for one of ordinary skill in the art to modify Hirao's starch solution using

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carbopol taught by Douglas. The unexpected result is free flowing crystal having desire size and shape.

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al., in view of Staniforth WO 96/23485.

Hirao is relied upon for the reasons stated above. Hirao does not teach the size range of the crystallized solid.

Staniforth teaches carrier particles useful in dry powder inhalers comprising one or more crystalline sugars including lactose, having particles diameter between from 60 μm to 180 μm (page 10, lines 2-17). Thus, it would have been obvious for one of ordinary skill in this art to modify Hirao crystalline solid carrier to have the particle size suitable for inhalation in view of the teachings of Staniforth, because the references teach the advantageous result in the use of crystalline sugars in pharmaceutical art. The unexpected result is a crystalline composition that is non-hygroscopic, free flowing, and can be in any desire size and shape.

Response to Arguments

Applicant's arguments filed 09/16/03 have been fully considered but they are not persuasive.

Applicant alleges that the crystal prepared according to the presently claimed invention have significantly higher mean elongation ratio and surface smoothness as discussed on page 10 of the present specification. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that

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the features upon which applicant relies (i.e., significantly higher mean elongation ratio and surface smoothness) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

To place the application in condition, the examiner suggested to incorporate the limitation of claim 50 into the generic claim 42. No agreement was reached.

Claims Allowable

Claims 50 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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